

REMARKS

Claims 217-241 are pending in the application. Support for the newly added claims 217-243 can be found throughout the specification, in particular claims 1, 2, 3, 9, 21, 34, and 39 as originally presented. All of the claims derive basis from previously submitted claims. Support for “non-adsorbent surface” in claims 222, 225, and 241 can be found, *inter alia*, at paragraph 91 in the patent application publication number US2005/0148101. No new matter has been inserted into the application.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-3, 9, 21, 34, 39, 205, 209, and 215 have been rejected under 35 U.S.C. §112, Second Paragraph, as being indefinite. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Claim 1 has been rejected because Examiner considers Claim 1 to lack a clear preamble. Claim 1 is also criticized for recitation of “allowing” and “the ability”. The Examiner considers these terms to be vague and indefinite terms. Examiner also indicated that a step of contacting the colloid particle with the non-colloidal structure is missing. The Examiner also objects to the use of language such as “relative to”, “auxiliary”, and “the target”. While applicant disagrees with Examiner on these issues, the newly presented claims amend or remove the objected to language. Therefore, it is believed that this objection has been overcome.

Rejection Under 35 U.S.C. §102(b) Over Ching '428 (EP 0299428)

Claims 1, and 9 have been rejected under 35 U.S.C. §102(b) as being anticipated by Ching '428. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Ching '428 discloses specific binding assay methods, kits and devices utilizing chromatographically mobile specific binding reagents labeled with colloid particles. However, Ching '428 fails to disclose using various signaling entities bound to the colloidal particles. Therefore, Ching '428 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §102(b) Over Olsen '335 (US 4,853,335)

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Olsen '335. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Olsen '335 discloses a sandwich immunoassay method which comprises a colloidal gold labeled binder specific for epitopes or receptors of a ligand, nonporous particulate solid phase which have antiligand covalently attached, and which are combined with the biological specimen or extract. However, Olsen '335 fails to disclose attaching a signaling entity to the colloid or providing an agent that links to a non-colloidal structure and the binding partner of the agent linked to the colloid particle and allowing the agent to be the intermediary in the binding between the colloid particle and the non-colloidal structure. Therefore, Olsen '335 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §102(b) Over Hansen '401 (US 5,589,401)

Claims 1, 9 and 205 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hansen '401. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Hansen '401 discloses a homogeneous immunoassay method for simultaneous determination of one or more antibody, antigen or hapten analytes in a fluid sample. However, Hansen '401 fails to disclose or suggest attaching a signaling entity to a colloid particle. Therefore, Hansen '401 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §102(e) Over Sigal '670 (US 6,319,670)

Claims 1-3, and 9 have been rejected under 35 U.S.C. §102(e) as being anticipated by Sigal '670. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Sigal '670 discloses a method of conducting electrochemiluminescence binding assays. Sigal '670 uses microparticles that include electrically conductive material. The electrically conductive material has one or more copies of an assay ligand immobilized on its outer surface and a plurality of electrochemiluminescent moieties immobilized on its outer surface. However, Sigal '670 fails to disclose or suggest using a signaling entity that is not a electroactive molecule or a electrochemiluminescent moiety on the surface of the colloid. Therefore, Sigal '670 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §102(e) Over Virtanen '349 (US 6,342,349)

Claims 1, 9 and 215 have been rejected under 35 U.S.C. §102(e) as being anticipated by Virtanen '349. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Virtanen '349 discloses an optical disk-based assay device in which analyte-specific signal elements are disposed on an optical disk substrate. However, Virtanen '349 fails to disclose or suggest a signaling entity attached to a colloid particle. Further, Virtanen '349 fails to disclose or suggest using a non-covalent linkage between the colloid and the non-colloidal structure. Accordingly, Virtanen '349 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §102(e) Over Bamdad '617 (US 6,541,617)

Claims 1-3, 205 and 209 have been rejected under 35 U.S.C. §102(e) as being anticipated by Bamdad '617. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Bamdad '617 discloses particles comprising binding ligands and electron transfer moieties. However, Bamdad '617 fails to disclose or suggest providing an agent linked to a non-colloidal structure and a binding partner of the agent linked to the colloid particle, and wherein the agent acts as intermediary to the binding between the colloid particle and the non-colloidal structure. Therefore, Bamdad '617 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §102(e) Over Oberhardt '615 (US 6,251,615)

Claims 1 and 39 have been rejected under 35 U.S.C. §102(e) as being anticipated by Oberhardt '615. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Oberhardt '615 discloses a method of analyzing cells in a carrier solution in which cells are attached to a surface and probed with a fluorescent antibody or an antibody attached to a fluorescent particle. However, Oberhardt '615 fails to disclose or suggest attaching a signaling entity to the colloid particle. Accordingly, Oberhardt '615 fails to anticipate the presently claimed invention.

Rejection Under 35 U.S.C. §103(a) Over Ching '428 in view of Charvch '556 (US 6,001,556)

Claim 21 has been rejected under 35 U.S.C. §103(a) as being unpatenatable over Ching '428 in view of Charvch '556. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Ching '428 is discussed above.

Charvch '556 is cited for the disclosure of a competitive assay in which a drug candidate is introduced to the system containing a receptor and its reciprocal binding partner.

Applicant asserts that the combination of Ching '428 and Charvch '556 fails to arrive at the presently claimed invention. In one aspect, Ching '428 fails to disclose a signaling entity attached to a colloid particle. In another embodiment, Ching '428 fails to disclose or suggest using a non-adsorbent surface substrate as the non-colloidal structure. Since Charvch '556 cannot remedy these deficiencies that are present in Ching '428, these references fail to be

combinable with each other to arrive at the presently claimed invention. Therefore, the presently claimed invention is not obvious over these cited references.

Rejection Under 35 U.S.C. §103(a) Over Sigal '670 in view of Altieri '389 (US 6,346,389)

Claim 34 has been rejected under 35 U.S.C. §103(a) as being unpatenatable over Sigal '670 in view of Altieri '389. Applicant traverses this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Sigal '670 is described above.

Altieri '389 is cited for the disclosure of a Glutathione-S-Transferase fusion protein. Applicant asserts that in view of the fact that Sigal '670 fails to disclose or suggest a signaling entity other than an electroactive molecule or electrochemiluminescent moiety, which deficiencies are noted above, fails to be combinable with the Altieri '389 references that discloses the well known Glutathione-S-Transferase protein to arrive at the presently claimed invention which uses signaling entities that are not electroactive molecules or electrochemiluminescent moieties. Therefore, the presently claimed invention is not obvious over these cited references.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. **502486** for any fees required under 37 CFR § 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. **502486**.

Respectfully submitted,

JHK Law

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